

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

To:

see form PCT/ISA/220

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference see form PCT/ISA/220		FOR FURTHER ACTION See paragraph 2 below	
International application No. PCT/US2005/008049	International filing date (day/month/year) 09.03.2005	Priority date (day/month/year) 09.03.2004	
International Patent Classification (IPC) or both national classification and IPC C07D471/04, C07D498/04, A61K31/437, A61P25/24			
Applicant CORCEPT THERAPEUTICS, INC.			

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application



2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

<p>Name and mailing address of the ISA:</p> <div style="text-align: center;">  <p>European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465</p> </div>	<p>Authorized Officer</p> <p style="text-align: center;">Seelmann, I</p> <p>Telephone No. +49 89 2399-7480</p> <div style="text-align: right;">  </div>
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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US2005/008049

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search ... (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
☐ a sequence listing
☐ table(s) related to the sequence listing
 - b. format of material:
☐ in written format
☐ in computer readable form
 - c. time of filing/furnishing:
☐ contained in the international application as filed.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

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Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application,
- ☒ claims Nos. 29-31 (industrial applicability)

because:

- ☒ the said international application, or the said claims Nos. 29-31 relate to the following subject matter which does not require an international preliminary examination (*specify*):

see separate sheet

- ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):
- ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
- ☐ no international search report has been established for the whole application or for said claims Nos.
- ☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:
 - the written form ☐ has not been furnished
 - ☐ does not comply with the standard
 - the computer readable form ☐ has not been furnished
 - ☐ does not comply with the standard
- ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.
- ☐ See separate sheet for further details

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Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	12,13,15-19,23-26,28-31
	No: Claims	1-11,14,20-22,27,32
Inventive step (IS)	Yes: Claims	12,13,15-19,23-26,28-31
	No: Claims	1-11,14,20-22,27,32
Industrial applicability (IA)	Yes: Claims	1-28,32
	No: Claims	

2. Citations and explanations

see separate sheet

**WRITTEN OPINION OF THE
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AUTHORITY (SEPARATE SHEET)**

International application No.

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Re Item III

Claims 29-31 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(I) PCT).

Re Item V**1. PRIOR ART**

Reference is made to the following documents:

D1: WO 03/061651 A

D2: EP-A-0 375 210

2. NOVELTY

The subject-matter of the claims is anticipated by D2 (Article 33(2) PCT). D2 discloses in claim 1 a generic formula which overlaps with the generic formula of present claim 1. Furthermore, the compounds of Examples 2-4 of D1 fall within this overlap. Therefore, the following claims are not considered as new: 1-11,14,20-22,27,32.

3. INVENTIVE STEP

The novel subject-matter of the claims can be considered as involving an inventive step (Article 33(3) PCT). The document D1 is regarded as being the closest prior art to the subject-matter of claim 1. It discloses tricyclic ligands for the corticoid receptor, which differs from the present compounds in that only one of the rings is heterocyclic, no isoquinoline moiety is present. The problem to be solved by the present invention is seen in the provision of further tricyclic derivatives as ligands for the corticoid receptor. In view of the experimental part and the other information as given in the description, it can be assumed that this problem has been solved for those compounds as disclosed in the claims. The prior art D2 gives no indication that the disclosed compounds possess an activity as ligands for the corticoid receptor. Therefore, D1 and D2 together would give no

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information, which would motivate a man skilled in the art to arrive at the present invention.